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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/825,210		04/16/2004	Takahiro Ishikawa	24-014-TB	7261	
23400	7590	07/24/2006		EXAMINER		
POSZ LAV	V GROUI	P, PLC	KRISHNAN, GANAPATHY			
12040 SOUT SUITE 101	ΓΗ LAKE	S DRIVE	ART UNIT	PAPER NUMBER		
RESTON, V	/A 2019	1		1623		

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

			Application No.		Applicant(s)			
		10/825,21	10/825,210 ISHIKAWA		L.			
Office Action Summary		Examiner	Examiner		Art Unit			
		Ganapathy	/ Krishnan	1623				
Period fo	The MAILING DATE of this communica	tion appears on the	cover sheet with	h the correspondence a	ddress			
A SH WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR CHEVER IS LONGER, FROM THE MAI resistance of time may be available under the provisions of SIX (6) MONTHS from the mailing date of this community openiod for reply is specified above, the maximum statutive to reply within the set or extended period for reply will reply received by the Office later than three months after ed patent term adjustment. See 37 CFR 1.704(b).	LING DATE OF TH 37 CFR 1.136(a). In no eve cation. ory period will apply and wil , by statute, cause the appli	IIS COMMUNIC ent, however, may a rep II expire SIX (6) MONT ication to become ABA	ATION. ply be timely filed  HS from the mailing date of this NDONED (35 U.S.C. § 133).				
Status								
1)⊠ 2a)□ 3)□	Responsive to communication(s) filed of This action is <b>FINAL</b> . 2b) Since this application is in condition for closed in accordance with the practice	D⊠ This action is not allowance except	on-final. for formal matte		ne merits is			
Dispositi	ion of Claims							
5)□ 6)⊠ 7)□	Claim(s) <u>1-6</u> is/are pending in the appli 4a) Of the above claim(s) is/are Claim(s) is/are allowed. Claim(s) <u>1-6</u> is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction	withdrawn from cor						
<b>A</b> pplicati	on Papers							
10)⊠	The specification is objected to by the E The drawing(s) filed on <u>16 April 2004</u> is. Applicant may not request that any objection Replacement drawing sheet(s) including the The oath or declaration is objected to be	/are: a)⊠ accepted on to the drawing(s) be e correction is require	e held in abeyanced if the drawing(s	e. See 37 CFR 1.85(a). i) is objected to. See 37 C	OFR 1.121(d).			
Priority ι	ınder 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.								
Attachmen <sup>.</sup>	t(s)							
2) 🔲 Notic 3) 🔲 Inforr	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO nation Disclosure Statement(s) (PTO-1449 or PT r No(s)/Mail Date	-948) O/SB/08)		mmary (PTO-413) /Mail Date ormal Patent Application (PT _·	<sup>-</sup> O-152)			

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#### **DETAILED ACTION**

### Claim Objections

Claim 4 is objected to because of the following informalities: Claim 4 recites sodium acetate as one of the Markush members for polar solvents. Sodium acetate is a salt and not a solvent. Appropriate correction is required.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the separation of glycolipids using a combination of chloroform, methanol, water and pyridine as solvents, does not reasonably provide enablement for the same for any and all other solvent combinations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

- (A) The breadth of the claims
- (B) The level of one of ordinary skill

(C) The amount of direction provided by the inventor

(D) The existence of working examples

(E) The level of predictability in the art

(F) The quantity of experimentation needed to make or use the invention based on the

content of the disclosure.

The breadth of the claims

Instant claim 1 is drawn to a method of separating glycolipids comprising contacting a

sample solution via a semipermeable membrane with a solution having a lower osmotic pressure

till the sample solution separates into two or three layers and separating the middle and/or

bottom layer. The sample solution and the solution of lower osmotic pressure as instantly recited

are broad and are seen to include any solvent or combination of solvents.

The level of one of ordinary skill in the art

The level of skill of those in this art is that of one having experience in organic

synthesis/separation.

The amount of direction provided by the inventor

The instant specification is not seen to provide adequate guidance, which would allow the

skilled artisan to extrapolate from the disclosure and examples provided, to use the claimed

method commensurate in scope with the instant claims. There is a lack of data and examples that

adequately represent the claims as written.

The existence of working examples

The working examples set forth in the instant specification are drawn to extraction of

glycolipids from mice via dialysis of a sample solution wherein the sample solution comprises a

combination of chloroform/aqueous methanol and pyridine and wherein the solution of lower

osmotic pressure is distilled water. The sample solution already has three immiscible solvents to

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begin with. One of ordinary skill in the art will not extrapolate this to a combination of any other solvent since the examples provided are not representative of any other solvent combinations encompassed by the broad recitation of instant claim 1.

### The level of Predictability in the Art

Partitioning of samples can be partial or total and depends on the solvents used and the nature of the sample and its solubility differences in solvents used. Just because a sample is highly soluble in one solvent does not mean it will be soluble to the same extent in another similar solvent.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to represent any or all solvent combinations encompassed by the recitation of the instant claims. One of ordinary skill in the art would have to carry out undue experimentation to practice the instant invention. One of ordinary skill in the art would be required to perform undue experimentation to determine which, if any, of the several solvent combinations would be useful to separate the glycolipids recited in instant claim 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 recites hydrolysis of an extract derived from a biological sample with a mixture of polar and non-polar solvents. It is not clear how using a solvent alone performs hydrolysis.

The claim recitation is unclear as to what applicants mean.

#### Conclusion

## Claims 1-6 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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GK

Shaojia Jiang
Supervisory Patent Examiner
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